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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,123	10/20/2000	Michael C. Barney	661005.90268	7800

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,123

Applicant(s)

BARNEY ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged if applicants' amendment B, request for extension of time and IDS, all filed 11/25/2002.

Claims 6 and 7 have been canceled per applicant's amendment B. Claims 1-5 are pending in the application.

1. The Standing Rejections:

Claim Rejections - 35 USC § 103:

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,313,178 ('178) by itself or in combination with US 6,183,763 ('763).

US '178 teaches a composition and method for inhibiting the *Staphylococcus aureus* growth. The method comprises contacting the bacteria with an effective amount of hexahydrolupulone (hexahydro-beta acid) or tetrahydroisohumulone (tetrahydroiso-alpha acid). The composition is formulated in an aqueous base water, alcohol, propylene glycol or glycerin. The composition is suitable for topical administration to the epidermis (abstract; col.1, lines 30-35; col.2, lines 1-57; col.3, lines 57-62; col.4, lines 63-67; col.5, lines 42, 54-57; col.7, lines 25-29).

US '178, however, does not teach the inclusion of alpha and beta acids and their derivatives in diapers or wipes.

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It is well known in the art to include antimicrobial agents in the diapers and wipes to inhibit the bacterial growth.

US '763 teaches an antimicrobial wipes effective against gram-positive bacteria like staphylococcus aureus (abstract; col.3, lines 9-11, 58-60). The reference disclosed hops extract as one of the antibacterial agents to be included in the wipe (col.9, lines 11-18).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to include alpha and beta acid derivatives in diaper or wipes with reasonable expectation of success of controlling staphylococcus aureus infection, and consequently, controlling toxic shock syndrome toxin-1 and toxic stress syndrome. Motivation would arise from the teaching of US '178 that alpha and beta acid derivatives are effective in inhibiting the growth of the Staphylococcus aureus bacteria or from the secondary reference teachings that hops extracts can be included in the diapers and wipes to inhibit staphylococcus infection.

2. *Response to Arguments*

Applicant's arguments filed 11/25/2002 have been fully considered but they are not persuasive.

Applicants' Arguments:

- US '178 teaches hydrogenated lupulones or derivatives for killing cancer cells and are delivered to each layer of skin, while the present invention directed to

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inhibiting the bacterial growth upon the surface of the skin and not dependent upon transdermal penetration. The dry surface layer of the present invention is different from topical cream or ointment taught by the reference. It is not obvious to one skilled in the art that application of the claimed compounds to liquid in contact of the infant by way of surface layer incorporating the claimed compound would be beneficial especially for inhibiting toxic shock syndrome.

- US '763 does not teach diaper, and does not make up for the deficiencies in US '178.

Examiner's Position:

- US '178 teaches the same compounds (alpha-acid or beta-acid) claimed by applicants and used for the very same purpose, i.e. method for inhibiting bacterial growth, col.2, lines 1-3. The reference teaches the effectiveness of the compounds against gram positive bacteria such as *Staphylococcus aureus*, and subsequently inhibiting toxic shock syndrome. The reference teaches clearly that the compounds are delivered topically to the epidermis (col.2, lines 1-3; col.5, line 54), as well as transdermally (col.5, lines 66-67). Treating cancer by applying the compounds transdermally is only one of the uses of the compounds. The composition disclosed by the reference that is suitable for topical application to the epidermis comprising the compounds in aqueous (water or alcohol) or oily (glycerin or glycols) base, same as disclosed by applicants, and it is within the

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skill in the art to select the way of applying the formulation, either on surface of dry diaper or a piece of dry gauze. Claiming a new use, new function, or unknown property which is inherently present in the prior art does not necessary make the claim patentable. Thus, the claimed compounds are disclosed by the prior art to inhibit the bacterial cell growth, especially gram positive, and more specifically *Staphylococcus aureus*, and one having ordinary skill in the art would use them in treating any infection caused by *Staphylococcus aureus*, such as toxic shock syndrome.

- US '763 teaches an absorbent wipe (col.3, lines 13-14) incorporating antimicrobial agents, such as hops, to clean the skin, and this would have motivate one having ordinary skill in the art at the time of the invention to use the antimicrobial agents into the surface of any other absorbent article such as a diaper, since both absorbent articles used for the same purpose, with reasonable expectation of success of the delivered article to inhibit toxic shock syndrome caused by *Staphylococcus aureus*. The use of the patents as references is not limited to what he patentees describe as their own inventions, or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain and to what it would suggest to one versed in the art.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,284,261 disclosed a diaper or wipe comprising antimicrobial

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agent to inhibit *Staphylococcus aureus*. US 6,262,038 disclosed a baby wipes comprising alpha-hydroxy acids. US 5,840,760 disclosed the control of staphylococcus infection by impregnation of antimicrobial agent into a diaper.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048.

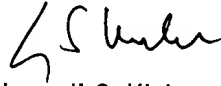
The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600